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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,874	02/22/2002	Brian Robert Walker	674543-2001.3	2506
20999	7590	01/13/2005	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			GUCKER, STEPHEN	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/080,874

Applicant(s)

WALKER ET AL.

Examiner

Stephen Gucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Response to Amendment**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Lakshmi et al. ("Lakshmi"). Lakshmi teaches measuring the reductase activity of 11-Beta HSD1 (called 11-OR activities in the reference) from brain micropunches. Lakshmi discloses that NADPH increased the specific reductase activity by 4-fold (pages 1743-1744), meeting the broad limitations of the claim of determining whether a compound or composition is a regulator of intracellular glucocorticoid activity.

*Applicant's arguments filed 9/9/04 have been fully considered but they are not persuasive. Applicant fails to point out any claim limitation that is not met by the prior art of record. A brain micropunch is not equivalent to a homogenate as Applicant alludes. A brain micropunch is similar to a tissue slice, and does indeed reflect the in vivo activity of the enzyme in question. Furthermore, Applicant concedes that the reference measured the bidirectionality of the enzyme, which clearly meets the broad limitations of the claim (which recites, but does not limit the claim to, measuring the enzymatic activity in one direction).*

4. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Gomez-Sanchez et al. ("Gomez-Sanchez "). Gomez-Sanchez teaches the administration of carbenoxolone (an inhibitor of 11-Beta HSD1 reductase activity, see abstract of Gomez-

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Sanchez) to rat brain via intracerebroventricular (i.c.v.) infusion (page E1126). Gomez-Sanchez meets the broad limitations of the claim because Gomez-Sanchez measures the blood pressure of the rat receiving the inhibitor of 11-Beta HSD1 reductase activity as a determinant as to whether or not the compound or composition is a regulator of glucocorticoid activity (abstract and Figures 1-3).

*Applicant's arguments filed 9/9/04 have been fully considered but they are not persuasive. Applicant fails to persuasively point out any claim limitation that is not met by the prior art of record. Applicant argues that a different isoenzyme may produce the blood pressure rise observed by the prior art, but this assertion does not rule out the participation of the enzyme in question in the instant claim, particularly when the process steps of the prior art are encompassed by the instant claim (due to the broadness of the claim). The Examiner was not supplied with a copy of reference #65 mentioned in the declaration, so the Examiner could not evaluate this reference in relation to Applicant's assertion.*

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961. The fax phone number for this Group is currently (571) 273-8300.

SG

Stephen Gucker

January 10, 2005

Lorraine Spector

LORRAINE SPECTOR  
PRIMARY EXAMINER